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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ZEMAN, MARY K	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,018	ARAD ET AL.	
	Examiner	Art Unit	
	Mary K Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 12-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 July 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group II, claims 7-11 in the reply filed on 7/29/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-6 and 12-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/29/04.

Priority

This application is a 371 of PCT US00/19524. This application claims priority to two provisional applications. The two provisional applications do not provide an enabling disclosure for the elected invention of claims 7-11. Priority to those applications is denied.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The references cited in the international search report have been considered, but they are not listed on any PTO-1449, or 892.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The listed claims are drawn to methods of designing compounds wherein the method steps merely manipulate data without providing a concrete tangible and useful result. MPEP 2106: "For such subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts. See Alappat, 33 F.3d at 1543, 31USPQ2d at 1556-57 (quoting Diamond v. Diehr, 450 U.S. at 192, 209 USPQ at 10). See also Alappat 33 F.3d at 1569, 31 USPQ2d at 1578-79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing O 'Reilly v. Morse, 56 U.S. (15 How.) at 114-19). A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible and useful. See AT &T, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in State Street, 149 F.3d at 1373, 47 USPQ2d at 1601) and/or when a specific machine is being claimed (as in Alappat, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc)."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 7 is drawn to a method of designing a paclitaxel alternative composition. Lines 1-14 of claim 7 are preamble, setting forth the structure of the base alternative molecule. The only positive active step of the method is "using molecular modeling software on a computer to design said alternative composition." This step lacks any particular direction as to what is to be

done to the base structure to design the alternative, such that one of skill in the art would not be able to use the claimed method.

In In re Wands (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must make or use molecular modeling software on a computer to design said alternative composition. For the reasons discussed below, undue experimentation would be required to practice the claimed invention.

b) The specification provides guidance for synthesizing specific paclitaxel alternative compositions on pages 43-50.

c) The specification provides working examples of "designing" specific paclitaxel alternative compositions in examples 1 and 2.

d) The invention is drawn to methods of designing a paclitaxel alternative composition. Lines 1-14 of claim 7 are preamble, setting forth a verbal (not a diagram) description structure of the base scaffold of the alternative molecule to be used in the design. The only positive active step of the method is "using molecular modeling software on a computer to design said alternative composition." No specific structure of the finished alternative molecule is provided, nor is any direction given as to what should be "designed" on the description of the base scaffold provided by the preamble. No specific starting structure is provided. No specific additions, substitutions or deletions are provided.

e) Molecular modeling and design is a complex field, requiring a large amount of information, direction, testing, and confirmation. Paclitaxel has been shown to be a particularly difficult target for the design of analogues or alternatives. Moyna et al. 1997 (J Med Chem 40 p3305-3311) discusses the many difficulties in paclitaxel alternative design. Moyna notes that the conformation of the drug bound to microtubules has been difficult to obtain, and that several

physical models for the structure of the drug/ target interaction have been presented, which are not compatible with one another. The various models of the structure of paclitaxel make it extremely difficult to know which relates to bioactivity. Moyna details the extensive work performed to identify two analogs of paclitaxel with similar structure to the parent compound, and notes that their activity was not comparable to the parent compound. This is an indication of the difficulty in designing a compound related to paclitaxel that retains its bioactivity.

f) The skill of those in the art of molecular biology is high.

g) The prior art predicts that it is extremely difficult to design alternative compositions to paclitaxel, and that simple computer-implemented design methods are not adequate. Inventive skill is required in the adjustment and substitution of elements in the parent compound, and the compounds must be tested for their activity, as even well designed compounds may not behave as expected.

h) The claims are broad because they are drawn to methods of designing a paclitaxel alternative composition. Lines 1-14 of claim 7 are preamble, setting forth a verbal (not a diagram) description structure of the base scaffold of the alternative molecule to be used in the design. The only positive active step of the method is "using molecular modeling software on a computer to design said alternative composition." No specific structure of the finished alternative molecule is provided, nor is any direction given as to what should be "designed" on the description of the base scaffold provided by the preamble. No specific starting structure is provided. No specific additions, substitutions or deletions are provided.

The skilled practitioner would first turn to the instant specification for guidance to practice methods of "using molecular modeling software on a computer to design said alternative composition.". However, the instant specification does not provide specific guidance to practice these embodiments. As such, the skilled practitioner would turn to the prior art for such guidance, however, the prior art shows that such design of analogs or alternatives requires inventive decision making, skilled analysis and extensive testing. Finally, said practitioner would turn to trial and error experimentation to determine what structures to use, modify and improve upon in the design of the alternative. Such represents undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7, the metes and bounds of the claim are unclear. The only positive active method step of the claim is: "using molecular modeling software on a computer to design said alternative composition." The preceding 14 lines of the claim are preamble, which describe a scaffold structure of a base compound to be used in the design. The "using molecular modeling software" step lacks positive active recitations of what is to be done, and what specifically is to be designed. One of skill in the art would not be apprised of the specific steps to be taken, or what compounds are to be achieved.

Claims 8-10 do not remedy this problem, as these limitations affect the preamble, and not the design step.

The metes and bounds of claim 11 are unclear, as it is not known what structures are to be synthesized. Claims 7-10 do not clearly end with the design of a specific compound such that any could be synthesized. One could not synthesize something that is not disclosed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,693,374 discloses a series of tubulin binding ligands which seem to have similar structures to those to be used in the claimed methods.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P Woodward can be reached on (571) 272 0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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MARY K. ZEMAN
PRIMARY EXAMINER